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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

MYERS, CARLA J

ART UNIT PAPER NUMBER

1634

DATE MAILED: 08/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

08/974,584

Applicant(s)

CECH ET AL.

Examiner

Carla Myers

Art Unit

1634

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 10 August 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 09 August 2004. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☒ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 119-126.

Claim(s) withdrawn from consideration: 127.

8. ☐ The drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☒ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). filed 8/9/2004.
10. ☐ Other: \_\_\_\_\_

*Carla Myers*  
CARLA J. MYERS  
PRIMARY EXAMINER

Continuation of 2. NOTE: The amendment to claim 121 raises new issues under 35 U.S.C. 112, first and second paragraphs. With respect to 35 U.S.C. 112 second paragraph, it is unclear as to what is intended to be meant by "joined by" within the context of the claim and it is unclear as to what is intended to be encompassed by the structure of the nucleic acid in which SEQ ID NO: 477 is joined to structure f). For example, it is unclear as to whether SEQ ID NO: 477 is joined 5' and/or 3' to structure f) or whether SEQ ID NO: 477 may be joined to an internal nucleotide of structure f). It is also unclear as to whether SEQ ID NO: 477 is directly attached to structure f) or whether indirect attachment is also encompassed by the claims. The amendment also raises new issues under 35 U.S.C. 112 first paragraph, new matter. The response does not point to any particular pages/lines of the specification as providing support for the newly claimed embodiments. The claim as originally presented required that structure f) comprises SEQ ID NO: 477. However, there does not appear to be support in the specification as originally filed for the claim as amended to require that SEQ ID NO: 477 is joined to structure f). For example, the specification does not provide support for nucleic acids comprising structures a), b), c), d), and e) and further comprising "SEQ ID NO:477-structure f)", or "structure f)-SEQ ID NO: 477" or "SEQ ID NO: 477-Xn-structure f)" or "structure f)-Xn-SEQ ID NO: 477."

Continuation of 5. does NOT place the application in condition for allowance because: IN SUMMARY, with respect to the rejection under 35 U.S.C. 112, first paragraph (New Matter), Applicants traversed this rejection by stating that each of the elements of the claim are individually disclosed in the specification and thereby applicants should be entitled to a claim that requires each of the individually disclosed elements. However, the disclosure of an individual element in the specification does not provide basis for a genus of compounds which contain that element together with other elements. Applicants state that they are exercising their right to recite limitations in a combination. However, it is not applicants right to claim combinations that were not disclosed in the specification as originally filed. The disclosure of SEQ ID NO: 118, 139, 143, 144, 146, 147 and 16/17 alone or within a specific nucleotide sequence does not provide basis for the broader concept of a genus of nucleic acids having 60% identity to SEQ ID NO: 118 and comprising SEQ ID NO: 139, 143, 144, 146, 147, and 16/17. With respect to the rejection under 35 U.S.C. 112, first paragraph (Enablement), Applicants state that it is not the standard to require that the reader be able to identify all possible active variants, but only a reasonable number of variants without undue experimentation. It is asserted that since the specification teaches motifs, one would be able to determine which sequences outside of these motifs could be modified. However, the teaching of conserved motifs does not provide sufficient guidance to enable the skilled artisan to determine how modification of any amino acid within the encoded protein will effect the activity of the protein. Applicants response appears to indicate that any amino acid outside of the conserved motifs can be modified without altering the biological properties of the encoded three-dimensional protein. However, Applicants have not provided evidence to support this contention. Non-conserved amino acids also effect the overall structure and function of the protein. No guidance has been provided as to how to modify e.g. 6 out of 10 of the "non-conserved" amino acids without effecting telomerase catalytic activity. Again, Applicants have disclosed one nucleic acid within the presently claimed genus and this single nucleic acid is not representative of the genus of nucleic acids claimed. A disclosure of how to search for nucleic acids which fall within the scope of the claimed genus is not equivalent to teaching how to make and use a representative number of specific nucleic acids which fall within the claimed genus. Applicants comments regarding written description do not apply to the present rejection because the present rejection is NOT a written description rejection and the statutes for written description and enablement and the criteria for meeting these statutes are not interchangeable. Applicants comments regarding the obviousness-type double patent rejection are correct. The maintained rejection is over U.S. Patent No. 6,261,836 (not U.S. Patent No. 6,093,809). It is noted that the '836 patent claims nucleic acids encoding hTERT proteins and variants and fragments thereof and thereby encompass the presently claimed nucleic acids containing SEQ ID NO: 16/17, 139, 143, 144, 146 and 147. With respect to the rejections under 35 U.S.C. 102(e) over U.S. Patents '809 and '867, Applicants state that the cited patents correspond to applications to which priority is claimed. It is argued that if these patents are not considered to be enabling, then they may not be considered as prior art. But if the cited patents are enabling, then they would not constitute prior art. Applicants states that the patent office cannot have it both ways. However, neither may applicant. The cited art is enabling to the same degree that the present invention is enabled. Applicants response does not clarify why the prior art is or is not enabling or why the presently claimed invention is distinguishable over the prior art. Further, the '836 and '809 patents are enabling for the specific nucleic acids set forth therein which comprise the motifs of SEQ ID NO: 16/17, 139, 143, 144, 146 and 147. Applicants were not given priority to the '809 and '836 patents because these patents do not provide support for the presently claimed invention. It is noted that a claim as a whole is given a date of priority, rather than the individual components of the claim. The '809 and '836 patents do not provide basis for the concept of the presently claimed genus of any nucleic acid encoding a protein having 60% with an amino acid sequence of SEQ ID NO: 118 and comprise the sequences of SEQ ID NO: 16/17, 139, 143, 144, 146 and 147. With respect to the Linger and Lendvay rejections, Applicant states that the office has not shown that the references teach nucleic acids which have at least 60% identity to the claimed polynucleotides. However, the claims do not require nucleic acids which encode for proteins having 60% identity over the full length of SEQ ID NO: 118. Rather the claims require nucleic acids comprising "an amino acid sequence" (i.e., any fragment/length of amino acids) having at least 60% identity with SEQ ID NO: 118. Since the nucleic acids of Linger and Lendvay contain each of the recited motifs, these nucleic acids necessarily share at least 60% identity with "an amino acid sequence" of SEQ ID NO: 118.